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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,259	12/14/2001	Jung-Hwan Park	BVTP-P01-590	6122

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08/27/2003

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EXAMINER

SIRMONS, KEVIN C

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 08/27/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,259

Applicant(s)

PARK ET AL. *cn*

Examiner

Kevin C. Sirmons

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 16, 17 and 31-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-15 and 18-30 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11-13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Information Disclosure Statement

A telephone call was made to Agnes S. Lee to request a copy of each reference (paper No. 10) supplied to the office on 4/21/03. Applicant's attorney was unavailable for comment. Therefore, the examiner is requesting a copy of each foreign patent and non-patent documents supplied on 4/21/03.

Election/Restrictions

Claims 16 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected (Species I) as indicated by applicant during a telephone interview on 8/22/03, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15. Further applicant withdrew claim 31-54 in paper no. 15.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 12-14, 18, 20-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Allen et al U.S. Pat. No. 6,334,856.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e).

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This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Allen discloses a device for transport of molecules or energy across or into a biological barrier comprising: a plurality of microneedles, each microneedles formed of a first material and a second material (col. 4, lines 25-55, col. 11, lines 18-45, fig. 8f and fig. 9f), wherein the second material is dispersed throughout at least a portion of the first material or forms a portion of the microneedles (col. 11, lines 40-46 and figs. 8f and 9f); as to claim 2, (Polymer microneedles, col. 11, lines 40-46); as to claims 3 and 4, (col. 4, lines 48-54); as to claim 5, (col. 4, lines 54-57); as to claim 6, (col. 4, lines 25-55, col. 11, lines 18-45, fig. 8f and fig. 9f); as to claims 7 and 8, (see abstract, col. 2, lines 64-67, col. 7, lines 22-35 and see entire patent), as to claim 9, (col. 6, lines 25-41); as to claim 12, (col. 11, lines 41-46); as to claims 13 and 14, (col. 11, lines 40-46, figs. 8a-8d and 9e-9f); as to claim 18, (8d and 9f); as to claims 20 and 21, (col. 7, lines 66-67 and col. 8, lines 1-30); as to claim 22, (col. 4, lines 25-57); as to claims 23 and 24, (col. 5, lines 38-57); as to claim 25, (col. 4, lines 33-57, col. 5, lines 27-37 and col. 15, lines 25-30); as to claims 26 and 27, (see above rejection and col. 11, lines 40-46); as to claim 28, (see abstract and above rejection); as to claims 29 and 30, (see abstract, background of the invention, summary of the invention and Transport Control Components).

Claims 1 and 13-15, are rejected under 35 U.S.C. 102(e) as being anticipated by Allen et al U.S. Pat. No. 6,334,856.

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a plurality of microneedles, each microneedles formed of a first material (polymer) and a second material (drug/agent), wherein the second material is dispersed throughout at least a portion of the first material or forms a portion of the microneedles (col. 17, lines 13-23) as to claims 13-15, (col. 17, lines 13-23).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 18 and 19 are rejected under 35 U.S.C. 103(a) as being obvious over Allen et al U.S. Pat. No. 6,334,856.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104,

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together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Allen disclose a device for transport of molecules or energy across or into a biological barrier substantially as claimed except for the second material being dispersed homogeneously through the first material. Allen discloses that salt is dispersed in a polymer or metal (col. 11, lines 40-46). It would have been an obvious matter of design choice to disperse the second material homogeneously through the first material since applicant has not disclosed that dispersing the second material homogeneously solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the second material being dispersed heterogeneously through the first material.

Allen discloses the device substantially as claimed except for wherein the microneedles comprises an interior bore where the second material is located and wherein the second material comprises a drug. Allen discloses in figs. 2e, 3g and 4d microneedles, where a second material can be placed in the interior bore as similarly shown in figs. 8d and 9f. Further, Allen discloses (col. 17, lines 13-23) that biodegradable and non-biodegradable can be used as the entire drug delivery device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Allen to have an interior bore that has a second material which is a drug since Allen teaches that the microneedles can be formed of

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porous material (col. 5, lines 6-25) and/or cannels (2e, 3g, 4d, 8d and 9f) to permit the passage of fluid and/or solid material through the microneedles.

Allowable Subject Matter

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Allen discloses the device substantially as claimed except for the second material comprises rigid particles which enhance the mechanical strength of the microneedles compared to microneedles formed without the second material.

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.



Kevin C. Sirmons
Patent Examiner
8/23/03